

Proposal of an ISO/IEEE11073 Platform for Healthcare Telemonitoring: Plug-and-Play Solution with new Use Cases

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Abstract—Remote patient monitoring in e-Health is everyday closer to be a mature technology / service. However, there is still a lack of development in areas such as standardization of the sensor’s communication interface, integration into Electronic Healthcare Record systems or incorporation in ambient-intelligent scenarios. This work identifies a set of use cases involved in the personal monitoring scenario and highlights the related features and functionalities, as well as the integration and implementation difficulties found when these are to be implemented in a system based on the ISO/IEEE11073 (X73) standard. It is part of a cooperative research effort devoted to the development of an end-to-end standards-based telemonitoring solution. Standardization committees are working towards adapting the X73 standard to this emerging personal health devices market and use case identification is essential to direct these revisions.

I. INTRODUCTION

E-Health offers a wide range of solutions in patient telemonitoring where scenarios are built up with several device combinations for vital signal acquisition [1]. Personal and Body Area Network (PAN / BAN) are emerging as wireless communications advance. Nevertheless, these solutions are unpractical without the use of standardization [2]-[4].

ISO/IEEE11073 standards (X73) were designed to address Intensive Care Unit (ICU) scenarios [5]. Authors claim that X73 can be adapted to these personal telemonitoring [6], and analyze a set of Use Cases (UC) as a starting point to the identification of new requirements to contribute to standards advancement. This work is based on the *know-how* achieved in previous development and evaluation efforts.

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Unlike ICU scenarios, these emerging situations involve communications restrictions due to particular electronic features as low voltage-low power sensors and processors included in wearable Medical Devices (MD), or even wired or wireless technologies not yet supported by X73. This means that the communication protocols need to be lighter, avoiding long time communications and being efficient in terms of overhead, bandwidth and use of CPU [7]. With the existing technology this leads to the conclusion that the most of the system’s intelligence can not be placed near to the MDs or sensors that are monitoring the patient. In this way, the new features of the e-Health scenarios are driving a deep review of the X73 standards, envisioning a new profile for Personal Health Devices (PHD) communications [8].

Use cases proposal and implementation is likely the best way to detect disagreements between the X73 standard and the needs in e-Health scenarios, as well as to foresee potential solutions. Identified needs are systems based on a standard protocol, where each module can be replaced by a similar standard-one, taking advantages of Plug-and-Play (P&P) capabilities for a simple configuration. Data should flow seamlessly from a sensor in the patient’s home to a hospital, interacting with the patient’s Electronic Healthcare Record (EHR). In short, bringing up advantages in costs, interoperability, comfort, and system usability for patients.

Besides the use cases, this paper describes a prototype platform where these functionalities are implemented and which is compliant with X73 and other standards (EN13606 or HL7). It is prepared to include (with minor modifications) features not yet supported by X73, such as wireless communications, and it is ready to adopt the planned changes brought to X73 by the PHD profile. Currently, this work is yet in a laboratory phase. The research group has been developing an X73 implementation focused in wired MDs (blood pressure and pulse-oximeter with USB/RS-232 connections) for controlled home scenarios, and a prototype based on wireless MDs (scale, ECG and pulse-oximeter with Bluetooth/RFID technologies) for personal sensor networks. Roadmap to the final development involves porting the software to developed personal health devices.

Use cases are presented in [Section II.](#), while the X73 platform is described in [Section III.](#) New functionalities and improvements based on the Ambient Intelligence (AmI) paradigm are described in [Section IV.](#) Finally, conclusions of the work are presented in [Section V.](#)

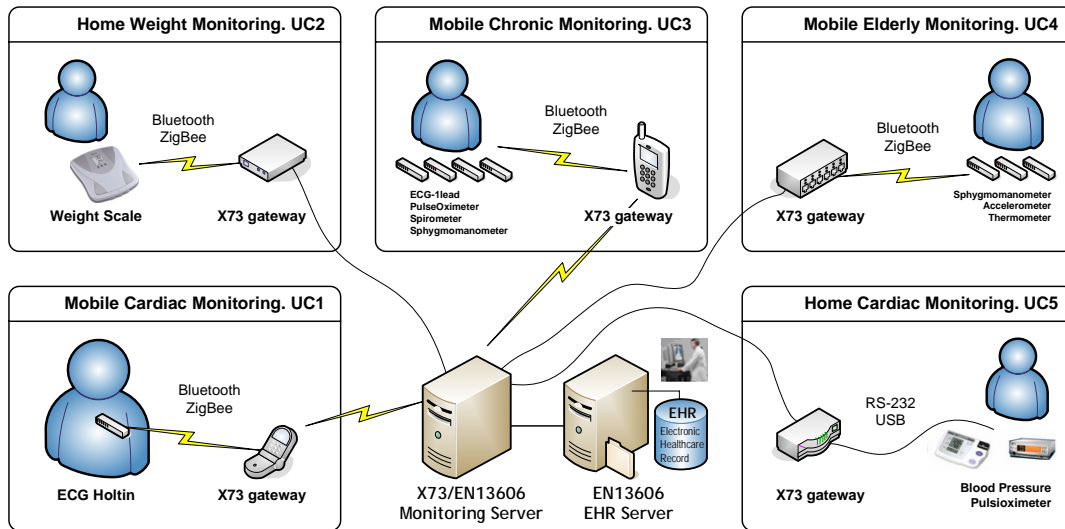


Fig. 1. UCs generic scheme

II. PROPOSAL OF NEW USE CASES

The proposed integrated solution that includes all these UCs is shown in Fig.1. The data from the different X73 MDs (according to each UC) is fetched in their X73 gateways, transmitted and managed by the X73/EN13606 Monitoring Server (MS), and stored in the EN13606 EHR server. The specific characteristics of each UC are following detailed:

A. UC1 – Mobile cardiac monitoring

A patient that suffers syncope or sporadic non perceptible symptoms of cardiovascular diseases could use the HOLTIN monitoring service [9]. The system is based on a native X73 wearable Holter device which controls the patient's ECG signal for long time periods in order to detect possible cardiac events. These events are transmitted, with Store-and-Forward (SF) scheme, to a X73-compatible mobile phone via Bluetooth and retransmitted to the MS by means of General Packet Radio Service (GPRS) technology, see Fig.1.

A front-end device located at the patient's chest performs both the acquisition of a modified ECG lead II (with a sampling rate of 200 samples/s) and the automatic detection of several cardiac events (tachycardia, bradycardia and asystolia) based on a QRS-detection algorithm. Moreover, a hand-triggered event is also possible if the patient notices he/she is having a specific symptom or suffers some syncope. Detected events are temporally stored in the device (up to 80 min.) for a later transmission to the gateway.

Setting of specific HOLTIN features as gain, cardiac event threshold values, signal store time for both automatic or hand-triggered event detection and patient data, can be configured by health professionals based on patient pathology. Likewise alarms and warnings are run on both front-end and X73 gateway informing about power supply, limit of memory, number of events, etc.

B. UC2 – Home weight monitoring.

A healthcare professional prescribes this use case when he/she is concerned about the patient's weight (situation very common in cardiac arrest patients). The connectivity between the X73-compatible weigh scale and the X73-gateway is achieved via Bluetooth or ZigBee, see Fig.1. Each time the patient follows the weighing protocol, her/his weight is transmitted to the X73-gateway and then to the MS via Internet. Once there, a specialist can access the MS to inspect the recorded data. The weigh scale is P&P and the patient only needs controlling the battery status.

C. UC3 – Chronic respiratory patient management

A patient with a chronic respiratory condition (typically COPD [10]) self-monitors her/his status, usually once a day. Monitoring results are: spirometry (main values and flow volume curve), oxygen saturation (pulse-oximeter), and answers to a symptoms questionnaire. In case the patient has a co-morbidity, typically coronary disease or diabetes, monitoring may as well include ECG, non-invasive blood pressure, and weight (cardiac) or blood glucose levels (diabetes). The service is prescribed for chronic respiratory patients and it may be used during an exacerbation episode or for longer periods. The case manager, with technical staff support, provides the patient with a cellular phone (see Fig.1) prepared with the monitoring application, as well as the spirometer and pulse-oximeter. The information is transmitted to the MS once the different data have been gathered (immediately after), and patient is warned if the transmission is not ok. The X73-gateway takes care of retransmission if necessary. Transmission is SF and is not time critical, provided that it is sent within the same day. Case manager checks patient's status daily and receives alarms triggered by the system. The service is supervised by the technical staff from the service provider which takes care

of the equipment. The gateway informs the patient if the monitoring MDs are not working properly (no batteries, device not connected or not working). Finally, warnings (SMS message, beeper call, email, web page) are issued if values are outside normal levels (personalized to the patient), if no data are received after a pre-established period, etc. Case manager or social worker may call the patient or pay a visit if needed.

D. UC4 – Elderly patient follow-up.

Similarly to UC3, the patient’s vital signs are controlled once a day using several sensors. There are two main differences between both use cases: 1) a wearable 3D accelerometer (that records patient movements during all day) is included to detect falls and/or to obtain a summary of her/his level of activity. 2) The gateway uses a fixed internet access to transmit data to the MS, as in UC1. As depicted in Fig. 1, note that data transmission between the X73-gateway and each of the sensors is wireless.

E. UC5 – Home cardiac monitoring.

A single patient concerned with his heart health at home wants his cardiac parameters to be controlled by a cardiologist. The patient has a weigh scale, a blood pressure and a pulse and oxygen saturation equipments installed at home using a fixed connection via RS-232 or USB, see Fig.1. Following the doctor’s advice, he has to use the equipment several times a day.

A summary of the technical characteristics required for every UC is detailed in Table I. From this new proposal, the following section presents the X73 integration methodology for a P&P solution.

TABLE I. TECHNICAL CHARACTERISTICS REQUIRED IN EVERY UC

	UC1	UC2	UC3	UC4	UC5
Communications					
X73-gateway possible inputs					
Wireless (Bluetooth, Zigbee, ...)	✓	✓	✓	✓	
Wired (RS-232/USB)			✓	✓	✓
X73-gateway possible outputs					
Wireless WAN	✓		✓		
Wired WAN		✓		✓	✓
Other features					
X73 sensor adapter- μ controller					✓
User warnings (SMS, e-mail, ...)			✓		
Battery status control	✓	✓		✓	
Faulty operation warnings	✓	✓	✓	✓	✓

III. X73 INTEGRATION FOR P&P SOLUTION

The UCs previously presented aim to be implemented end-to-end, following the X73 standard [2] and integrated in a homogeneous telemonitoring X73 platform, see Fig.1. The X73 standard enables this integration in a modular way by defining each Virtual MD (VMD), its specific Domain Information Model (DIM), its working mode (*baseline* or *polling*), its communication technologies, etc. However, the existence of X73 MDs is strongly conditioned to the vendors and manufacturers. Currently there are a high percentage of MDs that not implement the X73 standard. Moreover, although the proposed UCs will permit to integrate them when they become available, it is also difficult to find MDs with an X73-compatible physical output: at this moment, only RS-232 and IrDA are included in X73 standard (but most extended interfaces are not allowed the: USB or Bluetooth). Thus, in this development, proprietary MDs have been used with X73-adapters for the UCs proposed. These adapters implement the X73 standard on one side, and proprietary interfaces that can only be modified by knowing the vendor programming codes on the other side. The X73 MDs and adapters included in the proposed solution (see Fig. 2) are described as follows:

- *VMD1*. Intelligent Holter (HOLTIN) is a low voltage-low power customized wearable device supplied with a Li-Po rechargeable battery. An 8-bit microcontroller performs the main tasks (acquisition of ECG signal, detection and storage of cardiac events) and a Bluetooth chip enables the communication with the mobile phone (X73-gateway in UC1) without adapter. However, a native X73 implementation on HOLTIN is a handicap that has to be addressed, due to the current X73 version does not include Bluetooth (although this will change in the PHD profile), and it also will require the standard to be lighter to avoid excessive power consumption.

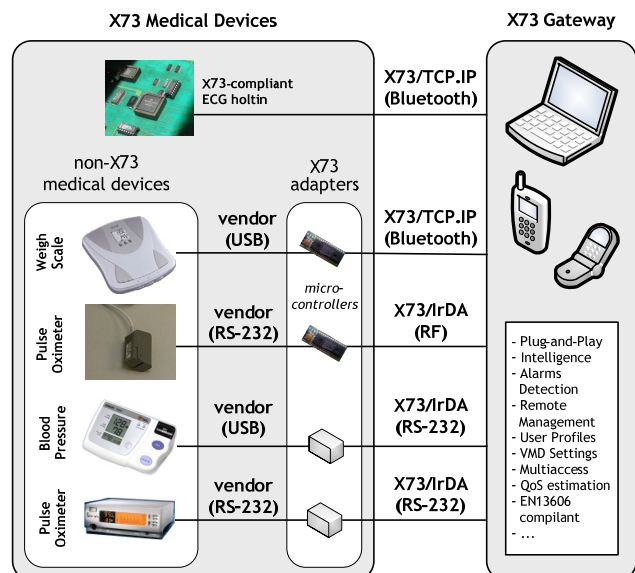


Fig. 2. MDs and X73-adapters considered in the solution

- **VMD2.** The TEFAL PP1015B0 is a battery-powered commercial weigh scale provided with a Liquid Crystal Display (LCD). An *ad-hoc* adapter has been developed and integrated into the weigh scale for UC2. The adapter consists on a Peripheral Interface Controller (PIC), which taps data from the LCD via USO input interface, and manages the VMD communication in polling mode profile via a Bluetooth output module over a TCP/IP connection. The limited processing capacity and ultra-low power consumption required are the challenges to be addressed.
- **VMD3.** It is based on a MEDLAB EG00302 OEM pulse oximeter that measures blood oxygen saturation (SpO₂), heart rate and plethysmographic waveform, and provides communication via RS-232 input interface. To configure the X73 VMD, an attached microcontroller-based module supports a RadioFrequency (RF) output interface for UC3 and UC4. Default working mode is baseline (UC3), although a polling profile can be added if combined with an extra microcontroller (UC4).
- **VMD4.** The OMRON 705IT measures asynchronously the blood-pressure and the pulse rate, with a 28 acquisitions memory. It provides a USB connection (that requires a RS-232 adapter for its fully X73-compliance in UC5).
- **VMD5.** The DATEX-Ohmeda 3900 is a pulse-oximeter with a RS-232 serial-port output (the only wired interface included in X73 description) that measures SpO₂, heart rate every 2s, and provides alarm support for UC5.

IV. AMBIENT INTELLIGENT FUNCTIONALITIES

The proposed X73 integration platform contributes to a P&P solution taking advantage of the X73 features in MDs interoperability. In order to improve the reliability and usability of this telecare platform, functionalities based on Ambient Intelligence paradigms have as well been considered in development. These AmI functionalities are:

- Quality of Service (QoS) analyzer module for evaluating the status of each internet access technology. As the number of MDs increases proportionally to the complexity of the monitoring scenario, the internet access must be properly managed, sharing the resources for each transmission's quality requirements. This module provides the possibility to adapt the transmission to the available bandwidth and required QoS.
- Alarm handling. X73 standard supports alarm reporting from MDs, so it is possible to trigger alarms on device and patient situations. Alarms can be reported to a healthcare professional when necessary, but could as well be handled by the patient at the gateway level. Intelligent alarm trigger on situations such as absence of patient response or detection of a worsening trend in vital signs is also possible.
- Personalized graphical and sensorial interface that helps guiding the patient in her/his monitoring procedure. Monitoring needs for a patient is gathered from the server that contains an up-to-date EHR file of the patient. This

functionality is based in two configuration files: *settings* (with the VMD/X73-adapter proprietary technical characteristics, detailed in [Table I](#)) and *profiles* (with the user -patient, doctor- requirements, detailed in the UCs presented in [Section II](#)).

V. CONCLUSION

The work towards interoperable telemonitoring devices based on standards is mandatory to achieve mature e-Health solutions that are not dependent on a single vendor. It is interesting to approach this work from the perspective of different research groups, as interoperability problems arise faster than in proprietary developments. Ambient Intelligence platforms running on X73 gateways will also provide new functionalities with the aim to control the PAN status overall, interact with the patient through dedicated interfaces and report any hardware faulty operations or suspicious patient status to a remote control centre.. It is clear that the absence of medical device P&P standards is an unacceptable barrier to innovation for safety and efficiency.

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Implementation Experience of a Patient Monitoring Solution based on End-to-End Standards

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Abstract—This paper presents a proof-of-concept design of a patient monitoring solution for Intensive Care Unit (ICU). It is end-to-end standards-based, using ISO/IEEE 11073 (X73) in the bedside environment and EN13606 to communicate the information to an Electronic Healthcare Record (EHR) server. At the bedside end a *plug-and-play* sensor network is implemented, which communicates with a gateway that collects the medical information and sends it to a monitoring server. At this point the server transforms the data frame into an EN13606 extract, to be stored on the EHR server. The presented system has been tested in a laboratory environment to demonstrate the feasibility of this end-to-end standards-based solution.

I. INTRODUCTION

INTENSIVE Care Units (ICUs) have been in last decades [1]-[3] the main bedside environment of hospitals where advances in technology have implied important changes in the Medical Devices (MDs), computers and sensors at the Point of Care (PoC). These devices acquire huge amounts of very valuable information, without the need for manually writing down each measurement, contributing to solutions based on the Electronic Healthcare Record (EHR) [4]-[6]. The communications within components of a patient monitoring system, and inter-system coordination become now very important in exploiting all the possibilities offered by the information gathered [7]-[9]. However, different manufacturers use their own software and communication protocols; building proprietary solutions that can only work alone or inside single-vendor equipment.

As pointed out at the EMBS06 [10], a standardized communication framework is necessary in order to solve the interoperability problem that now emerges. Two of the standards with research interest nowadays are ISO/IEEE 11073 for PoC-MDs Communications (also known as X73) [11], and EN13606 for EHR communication [12]; a brief overview can be found in [13]. X73 is a family of standards

for MDs interoperability. EN13606 is the European standard for EHR aiming to provide health care services in any part of the European Union. As opposed to other standards in the domain (i.e. HL7), the standard defines the architecture of an EHR network instead of a closed hospital environment. To the best of our knowledge there is no experience where the full chain from bedside monitoring devices to EHR has been implemented using standards. Even though there have been some initiatives to combine different standards, the vision of an entire end-to-end standard system is not yet a fact.

The system presented in this paper is a proof-of-concept design to show that it is feasible to create a patient monitoring solution for ICU environments that is end-to-end standards-based. Thus, ISO/IEEE11073(X73) has been used in the bedside environment and EN13606 to communicate the information to an EHR server. The components of this system (sensors, gateway, EHR server, etc.) can be replaced individually by equivalent standards-based devices with no need of system reconfiguration. In the case of bedside monitoring devices, this interoperability is *plug-and-play*.

This work aims to generate *know-how* and implementation guidelines to be used in future developments and to detect requirements that have not been addressed up to now. *Feed-back* will analyze how these implementations must be adapted to follow the future coming standard changes and how the standard can be improved to better fit real-world needs, especially keeping in mind telemedicine and home monitoring scenarios.

The paper is organized as follows. First, an overview of the architecture and design of the proposed system is given in Section II. The implementation experience according to X73 and EN13606 standards is detailed in Section III. The results of the implementation are discussed in Section IV.

II. SYSTEM ARCHITECTURE AND DESIGN

Figure 1 shows the proposed system architecture, including the fully standards-based prototype, which is made of independent interoperable modules. The generic design consists of several X73 MDs in the PoC related to the ICU. The information collected from these devices is integrated into a gateway. These X73 gateways from each PoC (even from others X73-sensors networks) interconnect with the monitoring server to manage the e-Health service. This monitoring server can also send the acquired patient information to the EHR server according to the EN13606 standard. The specific technical characteristics of each architecture element are following detailed.

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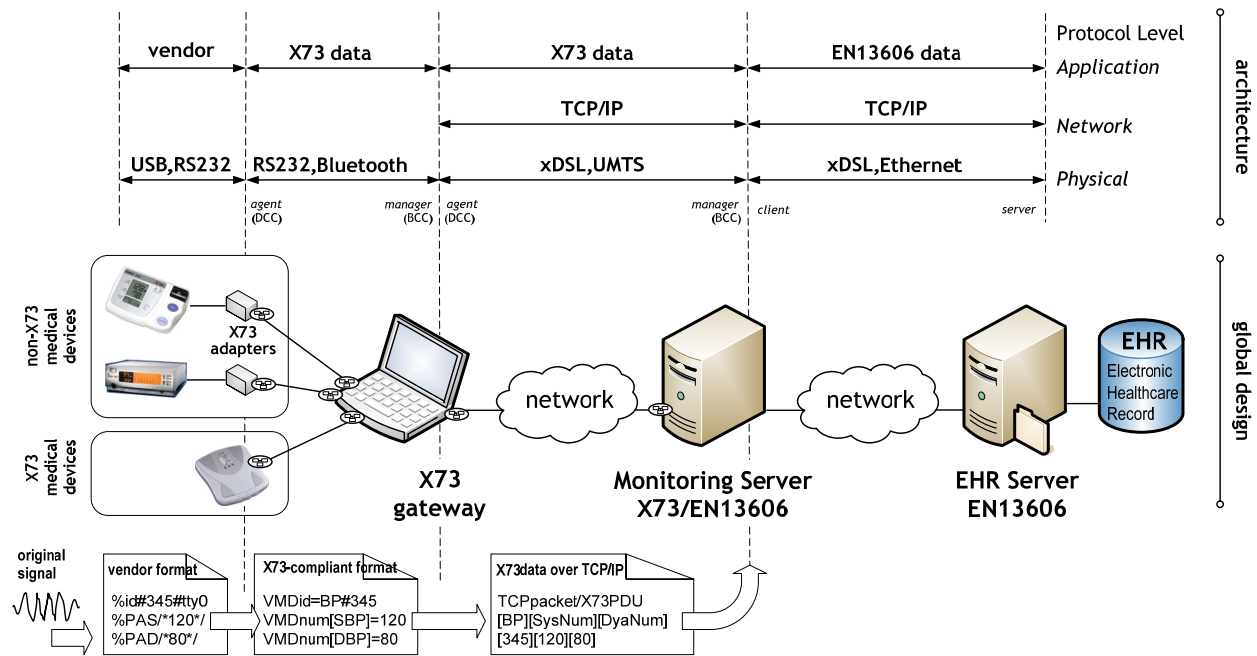


Fig. 1. Proposed end-to-end X73/EN13606 design scheme

A. X73 MDs and adapters

Currently there are no 100% compliant X73 MDs. In addition to this, it is difficult to find MDs with an X73-compatible physical output noticing that only RS-232 and IrDA are included in the X73 standards at the moment. Thus, in this development, proprietary MDs have been used together with an X73-adaptor which, on one hand implements the standard X73 and on the other hand, proprietary interfaces. These MDs are: *OMRON 705IT* (blood-pressure and pulse measurements with a USB output) and *DATEX-Ohmeda 3900* (pulse oximeter with a serial-port output). This adapter includes the main X73 modules: Medical Device Data Language (MDDL), Domain Information Model (DIM), and Dynamic Model (that provides the communication model (agent-manager) from 'Device Communication Controller' (DCC) to 'Bedside Communication Controller' (BCC) for interconnection between X73 adapter and X73 gateway).

B. X73 gateway

The designed gateway is an X73 access point. It supports a network of X73-compatible MDs measuring vital signs from different patients in different locations. The data acquired from the different sensors is transmitted to the X73 gateway which provides a logic module for the Medical Data Information Base (MDIB). This module allows monitoring and alert and measurement acquisition. Thus, following the X73 nomenclature, this gateway is represented as a Medical Device System (MDS): when each MDS is either connected or disconnected (*plug-and-play*) the MDIB is automatically updated and a MDS is created in the object hierarchy.

C. X73/EN13606 monitoring server

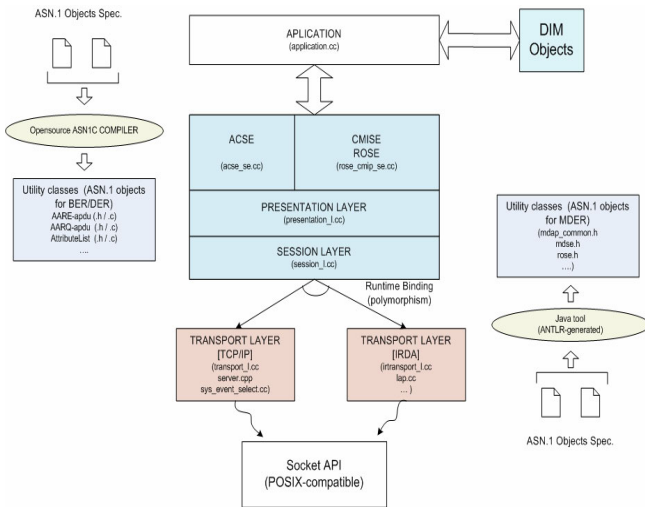
The monitoring provides a double role: *manager* for the communications with the X73 gateways, and *client* for the connections to the EHR server. Thus, it may belong to the ICU, the reference hospital, or can even be used as an external management server.

As a *manager* for the X73 gateways, the monitoring server manages the decision making in an intelligent way through several functions: automation of the data acquisition process, technological transparency (independent of the transmission modes of the X73 gateways), definition of patterns to identify, detection and management of anomalies (alarms, failures), patient specifications (decision thresholds, operation limits), updates and evolutions, etc.

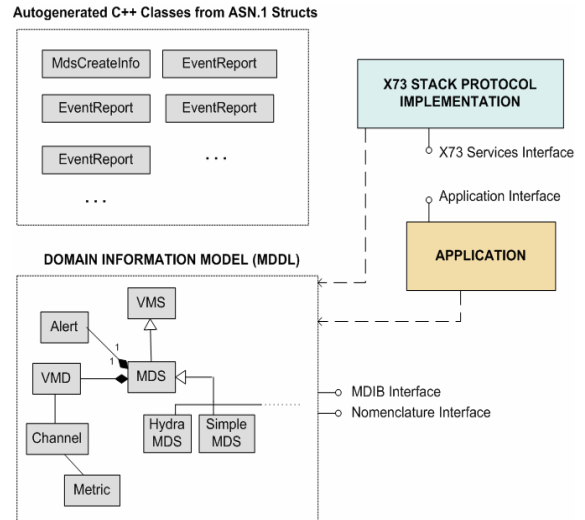
As a *client* for the EHR server, the monitoring server creates an EN13606 extract (from X73 data of the MDs) that is transmitted to the server in an intermediate archetype file.

D. EN13606 EHR server

The EHR server is a clinical information container that stores the databases that are associated with the EHR of each patient and updates them by incorporating the incoming information from the MDs in an EN13606 compliant format. Thus, it receives the archetype files with the EN13606 extract, validates this extract according to EN13606 standard, stores it in the appropriate EHR database, and sends back an acknowledgement to the client. This process traditionally has been studied in an isolated way as an EHR communications interoperability problem, but in this implementation experience it is integrated with the monitoring process to propose a entire end-to-end solution.



(a) Protocol stack scheme



(b) Block diagram

Fig. 2. X73 gateway and monitoring server implementation scheme

III. X73/EN13606 IMPLEMENTATION.

A. X73 implementation experience.

The complete implementation experience scheme is shown in Fig. 2. The programming framework basically consists of Java, C/C++ and Abstract Syntax Notation One (ASN.1) as a language for the exchange of messages coded with Medical Device Encoding Rules (MDER, proposed codification rules for X73).

Following a downwards process through the protocol stack, firstly, the application layer is defined by several protocols: ACSE (for association control), CMISE (for the basic services defined in VITAL) and ROSE (for the link between call requests and responses). Both ROSE and CMISE are merged into CMDISE. Secondly, the presentation layer is mainly a negotiation mechanism for the syntaxes used by higher layers: the *abstract syntax* to use (which set of messages are to be exchanged) is specified by MDDL, and the *transfer syntax* (how the messages are encoded) is described by the MDER. Thirdly, the session layer provides support to the ACSE (a simplified version). Finally, the implementation of the transport layer varies regarding TCP/IP or IrDA-cable protocol being in our case TCP/IP over RS-232 transmission. The implementation details are described as follows, step-by-step according to the message exchange among the different layers and using implementation scheme:

- 1) The DCC controller (*agent*) initiates a connection to the BCC controller (*manager*):

```
stack->transport->t_con_req(conn);
```

- 2) The BCC receives a connection request. It begins accepting incoming events and passes the request up to the application layer. The BCC starts an association request to the DCC.

```
→ transport_fsm::n_con_ind.
→ application_l::t_con_ind ()
→ acse_se::assoc_req
  (const st_buffer & buffer)
→ presentation_l::p_con_req
  (const st_buffer & buffer)
→ session_l::s_con_req
  (st_packet * packet)
→ transport_fsm::t_send_req
  (st_packet * packet)
```

- 3) The DCC receives an association request and sends a confirmative answer:

```
→ transport_fsm::buffer_received
  (const st_buffer & buffer)
→ session_l::t_data
  (const st_buffer & buffer)
→ session_l::s_CN ()
→ presentation_l::s_con_ind
  (const st_buffer & buffer)
→ acse_se::p_con_ind
  (const st_buffer & buffer)
→ application_l::assoc_ind
  (const st_buffer & buffer, &outbuffer)
```

- 4) The BCC receives the association confirmation:

```
→ transport_fsm::buffer_received
  (const st_buffer & buffer)
→ session_l::t_data
  (const st_buffer & buffer)
→ session_l::s_AC ()
→ presentation_l::s_con_cnf
  (const st_buffer & buffer)
→ acse_se::p_con_cnf
  (const st_buffer & buffer)
→ application_l::assoc_cnf
  (const st_buffer & buffer)
```

- 5) The connection procedure finishes. Now the entities exchange messages in conformance with the ROSE/CMIP protocol and ruled by the selected application profile (baseline or polling mode).

B. EN13606 EHR server implementation.

The proposed implementation experience is completed with the process of storing medical device information in the EHR server, fulfilling EN13606 standard. The client/server architecture has been implemented with *middleware* technologies, based on Web Services (WS). The employed tools are Apache Axis (open source), the Servlets/JSPs container Apache Tomcat, eXtensible Mark-up Language (XML, WS-based framework based on an implementation of the SOAP server), and various utilities and APIs for generating and deploying Web service applications. Data are transmitted using HTTPS protocol and, in order to gain security, the Apache WSS4J framework is used.

On the *client* side, a Java application has been developed. Its function is to read the MD data which is stored in an intermediate archetype file (XML document), by giving the EN13606 standard format using eXtensible Style sheet Language Transformations (XSLT) and making the call to the WS to store this information in the EHR. On the *server* side, a WS has been implemented. Its functionality is to receive the XML extract, in EN13606 format, sent by the client and to validate it, using XML Schemes. Once the XML extract is validated, an acknowledgement will be sent to the client. If it was successful, the extract will be stored in the EHR Server database.

IV. DISCUSSION AND CONCLUSIONS

The adoption of a complete standard end-to-end solution for patient monitoring inside hospitals can be extremely useful for the integration and interoperability of the huge amounts of vital data collected every day, making a more efficient use of such information, allowing it to be shared among professionals, giving more facilities for the mobility of patients within the hospitals, reducing costs and increasing usability for patients, health care professionals and manufacturers.

From this implementation experience it was seen that X73 implementation is feasible and the standard documents are reasonably understandable, however, some guidelines could be of great help for developers that want to apply standards to a specific system. In this case, and without previous experience, the implementation of the two standards in the whole system took no more than 3 months and it was performed by a group of 5 *soft/hardware* developers following the advice of the rest of the research group.

Some parts of the X73 standard are still subject to changes, and some layers are being adapted to improve its performance with different types of transmission technologies. The EN13606 standard is also evolving and changes in the domain information model are expected.

Home telemonitoring has experienced an important growth in the past years, and nowadays it has proved its efficiency as a follow-up option in scenarios such as chronic disease management, home hospitalization, follow-up after

ambulatory surgery, and elderly patients' care. Mobile telehealth solutions are expanding the limits of telemonitoring, allowing patient follow up while they carry out the activities of their daily living. The work presented in this paper can be adapted for the implementation and design of a standard end-to-end solution for medical device communications in home and ambulatory environments, having an important impact in this promising market. Standards-based telemonitoring devices are critical for the e-Health sector, as they can foster competitiveness between manufacturers and help service providers in a definitive adoption of telemedicine.

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Telemonitoring Systems Interoperability Challenge: An Updated Review of the Applicability of ISO/IEEE 11073 Standards for Interoperability in Telemonitoring

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Abstract— Advances in Information and Communication Technologies, ICT, are bringing new opportunities and use cases in the field of systems and Personal Health Devices used for the telemonitoring of citizens in Home or Mobile scenarios. At a time of such challenges, this review arises from the need to identify robust technical telemonitoring solutions that are both open and interoperable. These systems demand standardized solutions to be cost effective and to take advantage of standardized operation and interoperability. Thus, the fundamental challenge is to design plug-&-play devices that, either as individual elements or as components, can be incorporated in a simple way into different Telecare systems, perhaps configuring a personal user network. Moreover, there is an increasing market pressure from companies not traditionally involved in medical markets, asking for a standard for Personal Health Devices, which foresee a vast demand for telemonitoring, wellness, Ambient Assisted Living (AAL) and e-health applications. However, the newly emerging situations imply very strict requirements for the protocols involved in the communication. The ISO/IEEE 11073 family of standards is adapting and moving in order to face the challenge and might appear the best positioned international standards to reach this goal. This work presents an updated survey of these standards, trying to track the changes that are being fulfilled, and tries to serve as a starting-point for those who want to familiarize themselves with them.

I. INTRODUCTION

Patient telemonitoring is one of the most common practices in telemedicine in both indoor and outdoor scenarios, and it is hoped that it can increase the quality of the care and the efficiency of services provided. In fact, it should facilitate a continuous or event monitoring of chronic, elderly, under palliative care or have undergone surgery,

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without them occupying the beds that would be necessary for monitoring in-situ (leaving the beds for the use of patients in a more critical condition). In addition, telemonitored patients can continue to live in their own homes with the subsequent advantages: comfort, more favorable environment, less need for trips to the hospital, etc. Telemonitoring, used appropriately, is expected to decrease healthcare costs.

Two barriers to the current expansion of telemonitoring services, both related to interoperability, can be identified and, in our opinion, they make the transition from pilot experiences to clinical use very difficult: 1) Heterogeneity of devices and systems, and 2) difficulty of integration with healthcare information systems used routinely by healthcare professionals.

For that reason, it is desirable that non-patient oriented devices that form part of a spectrum of use from fitness and wellness monitoring, though devices in support of both independent and assisted living and into self-managed informal monitoring, are also capable of playing a part in such an interoperable continuum of care. As the paradigms for health management change in the face of societal and economic pressures this continuity and flexibility will become increasingly important.

The challenge? In order to be successful in this it will be necessary to follow a globally accepted standard that provides a standardized operation, allows interoperability and provides consistent semantics to recipient systems.

In this paper we provide a starting point and survey of ISO/IEEE 11073 as the best-positioned standard for Plug and Play interoperability of Personal Health Devices. Telemonitoring systems are overviewed in Section II, the option of using ISO/IEEE 11073 standards as the middleware is analyzed in Section III and their evolution is covered in Section IV. Finally, some conclusions are drawn in Section V.

II. TELEMONITORING SYSTEMS AT A GLANCE

There have been many different telemonitoring experiments, whether in the home (where the patient measures the necessary parameters and sends the signals to a telemedicine centre), ambulatory – sometimes called ubiquitous or m-health – where the patient uses a mobile device and can therefore undertake monitoring out of the

home, in controlled environments, such as geriatric residences, or in the framework of consultations with healthcare professionals, etc. Among the most advanced applications are the telemonitoring of diabetic patients [1], heart patients [2-4], respiratory patients [5, 6], and elderly patients [7]. In the majority of cases, the process consists of periodically acquiring vital signals (e.g. blood pressure or heart rate) and other biomedical signals (e.g. ECG signals) to record them locally (home or ambulatory) and later sending them to a remote telemedicine centre, where they are available for the consultation by a specialist or healthcare professional.

The devices used most frequently in telemedicine applications to measure parameters and biological signals are glucose meters, blood pressure and heart rate meters, pulse oximeters, ECG monitors, digital scales, etc. (see Figure 1). The devices can be fixed, but it is increasingly common for them to be wireless or “wearable” (with sensors incorporated into clothing, bracelets, etc.), that makes their use more comfortable. These collections of sensors around the patient make up what can be usually described as either a Body Area Network (BAN) or Personal Area Network (PAN). Often, for monitoring elderly patients or those with limited mobility, these PAN or BAN networks are completed with presence detectors, movement sensors, or similar ‘Telecare’ devices, which combine to form a Home Area Network (HAN).



Figure 1 - Typical medical measurement devices

There are two areas of integration that can be identified in the design of a Telemonitoring System that forms part of a Healthcare Information System or a general Telemedicine System:

a. In the local area of the devices, that is the BAN/PAN/HAN network where the patient is located, and where we can find heterogeneous monitoring devices (for example, a sphygmomanometer, scale, or pulse oximeter).

b. In the sphere of Telemedicine Systems, that is in the environment where the patient’s medical data has been received, and where, in order to be useful, they must be 1) integrated with the patient healthcare record and 2) accessible by professionals that are taking care of the patient.

The major difficulty in the area of the personal user network is to get different monitoring devices working as a homogeneous network. At present, the manufacturers of telemonitoring devices are using proprietary data exchange formats that are usually not made public. This situation makes it difficult to replace any device (either because they have become obsolete or that better sensors are available, or else because they do not have the necessary usability, do not function correctly, or just because of changes in the needs of

the user) when is needed, and also impedes adding new devices to a system without modifying the entire architecture. Any of these situations in one telemonitoring system entails major changes in the application software, not only because of differences in formats, but because the operation paradigm is usually very different. If we consider that is quite common for elements to be replaced, telemonitoring systems need to be designed so they can be integrated in telemedicine platforms in a simple way, as close as possible to the plug and play paradigm. To reach that objective, it is essential to use international standards that can be followed by different manufacturers of devices [8-10]. Avoiding proprietary formats will then decrease the costs in case of replacement, providing high scalability, which is a very important feature in systems that may vary their configuration. The systems can be more centralized and can manage the data captured from the different devices in a more efficient way.

The challenge of having telemonitoring systems that can interoperate and communicate with an open standard is complicated, somehow, because of the features of the devices that are usually implied. Devices and sensors in telemedicine scenarios are usually wearable [9]; these devices need to have some particular electronic features like low voltage-low power, in order to extend the autonomy, limited CPU, reduced size and light weight. Thus, there is a trade-off between the amount of data to be transmitted and these features. The communication protocols need to be lighter, avoiding lengthy communications and being efficient in terms of overhead, bandwidth and use of CPU [9]. With today’s means, this leads to the conclusion that the most of intelligence of the systems has to be located away from the MDs or sensors that are monitoring the patient.

For these telemonitoring devices, the transmission technologies may vary, and can be wired or wireless: (e.g. Bluetooth, Zigbee, Wibree, USB, RS-232, etc.). Furthermore, they coexist with other medical devices and network devices such as PCs, routers, modems, mobile phones, etc. that are using different technologies. Then a modular layer design of the standard should have specializations for different low layer communications that can be used.

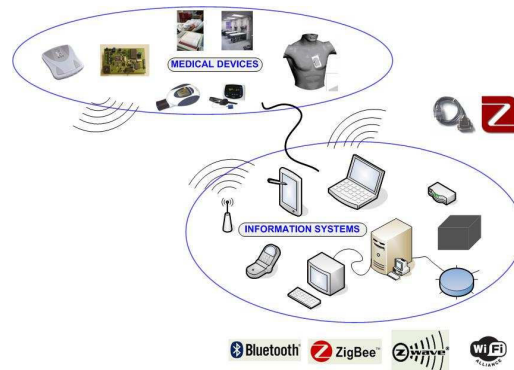


Figure 2 - Medical devices interoperability

It is also important to mention that a standard for medical device communications in telemonitoring scenarios can change the market and is critical for competitiveness between the different companies, manufacturers and service providers. At this point emerges Continua Alliance, which is a group of technology, healthcare and fitness companies that wish to increase compatibility of e-healthcare devices using the existing standards to create an interoperable framework. Their objectives are to design the guidelines to achieve interoperability of sensors and systems [11].

Currently there is no standard that tackles, specifically, the problem of integrating devices in home and ambulatory telemonitoring environments, but there is a family of standards which purpose is to increase the interoperability of medical devices at the point of care, and that are evolving to include these scenarios. Those are the EN ISO/IEEE 11073 Point-of-Care Medical Device Communication standards [12], which we review here.

To place the standard in context, we summarize other standards in the field of healthcare information systems oriented towards the encoding of signals and biomedical parameters, the standardization of the electronic healthcare record, or the communication between medical applications using standardized messages. Some of these standards are: POCT-1A2 (communication protocols between the device and an access point [12]), Health Level 7 (HL7, for the exchange, management and integration of electronic healthcare information [13]), DICOM-Digital Imaging and Communications in Medicine [14], and EN13606 (for EHR communication [15]).

III. ISO/IEEE 11073 AS A MIDDLEWARE

The ISO/IEEE 11073 PoC-MDC (also known as X73) is an internationally harmonized family of standards produced by a grouping of manufacturers, institutions and IEEE in association with ISO and CEN. It consolidates previous IEEE-1073 Medical Information Bus (MIB) [16] and CEN standards (VITAL [17] and INTERMED [18]).

The 11073 standards have been adopted as European standards and will soon be sufficiently complete to replace VITAL and INTERMED which are, formally still valid in Europe.

The European Committee for Standardization (CEN) [19] Technical Committee 251 (TC251) is responsible for health informatics and constitutes the only Europe-wide forum for consensus and standardization of computer science applied to healthcare [20]. It liaises closely with the International Standards Organization (ISO), the principal world standardization body, and for ongoing standardization efforts, the Vienna agreement avoids duplication of items between CEN and ISO.

The 11073 standards address different levels of the ISO OSI reference Model, and have reference models for access to the data, with services and communication protocols for interoperability between medical devices.

In accordance with the 11073 standards, interoperability in the local level of monitoring devices can be solved by connecting all of them with a central element that acts as a main connection integrated compute engine (CE) with the telemonitoring server (see Figure 3). This CE must control the interaction with the different medical devices that form the BAN/PAN network, and monitor the patient (by means of the configuration of the sending and reception of data and control information). In the same way, the CE will be in charge of connecting the patient network with the telemonitoring server. Of these connections, it is in the communication with the telemonitoring medical devices that compose the patient network where, if widespread use is to be achieved economically, the greatest need for standardization arises, homogenizing the interface between medical devices and the CE.

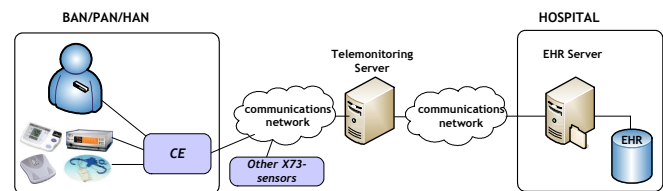


Figure 3 – Generic telemedicine integrating heterogeneous systems

In the other critical field of interoperability introduced earlier, integration of a telemedicine system into mainstream healthcare workflow and practice, the main challenge is in being able to incorporate information from perhaps disparate telemonitoring services that themselves include different vendor's medical devices and CEs, managed by the telemonitoring servers; each telemedicine system being connected to the generic Electronic Health Record. In this scenario, middleware technologies provide portability (a telemonitoring system can be connected to different telemedicine systems) and interoperability (medical applications in different clinical environments can exchange information between devices connected to the patient).

A common shortcoming, even when considering use of new technologies, is to overlook the importance of consistent representation of content. This has been a significant problem in the health sector with a number of attempts at achieving consistent representation of meaning having been attempted in the last 20 years or so [21-23]. For medical device communication the problem was recognized as being of major importance when a pan-European project team started work on VITAL [17] – it was simply not possible to correctly interpret between languages the extremely detailed terms being used. The concept of semantic links was adopted to build up language-independent means of describing these detailed concepts. This, allied to a robust information model of the domain [24] facilitated production of a globally usable medical device data language [25] crucial in a global industry fore both devices and health software systems.

The rigorous and extensible nature of the medical device

data language has been recognized and adopted [26 – 28] to enable large databases to contain physiognomic data for research and regulatory purposes. Work is currently underway to link these detailed representations to the less detailed terms clinicians customarily use – and that are represented in SNOMED CT [22].

It appears likely that only with true semantic interoperability from the device to the health record will it be possible to use operational health information alongside genomic and adverse event databases for data-mining and research to improve practice.

IV. HOW IS ISO/IEEE 11073 FACING THE CHALLENGE?

IEEE is developing ten telehealth device standards for controlling information exchange to and from personal telehealth devices and cell phones, personal computers, personal health appliances and other computer engines as a part of the ISO/IEEE 11073 family of standards.

The complexity and density of the documents that conform the bulk of the X73 family of standards is one of the key points that are restraining its adoption [29]. To overcome this, the new standards pretend to provide clear definitions of what is needed to implement common communication features for personal telehealth devices, defining also a common core of communication functionality for these devices, and specifying the use of term codes, formats and behaviors in a telehealth environment to favor plug-and-play interoperability.

The new telehealth standards projects are: A technical Report Overview, a Common Networking Infrastructure and an Optimized Exchange Protocol for Medical Device Communication of Personal Health Devices, as well as several Medical Device Specializations. According to IEEE, they will provide the mechanisms needed for real-time, plug-and-play interoperability and define comprehensive protocols and services for medical devices in networked operating contexts. [30]. The intention is then to face the challenge and respond evolving with a defined framework, a networking infrastructure and a light communication protocol, appropriated for the kind of Medical Devices, with the special features that we commented in section II, that are found in telemonitoring scenarios.

Due to the different communication technologies that can be used in such a scenario, the ISO/IEEE 11073 family of standards is trying to build a communication standard that is more or less independent of the transport. However, this may be a difficult task as the protocols could be more efficient by using some 'native' features of the communication transport technology that the exchanged information. Even so, the IEEE is making a big effort to solve this trade-off in the most efficient way. In that way, IEEE is building these new standards in collaboration with the Bluetooth SIG (MD-WG) [31], and USB, for example.

According to IEEE, this body of standards will serve a wide range of audiences including medical device and

system developers, those who deploy and manage healthcare systems and those who regulate their use, personal telehealth device and compute engine vendors, and institutions that use data from these devices. [30]

The ISO/IEEE 11073 standards are being developed with a high level of international participation and in collaboration with other standards to create interfaces and ensure compatibility between them, as it can be POCT-1A or HL7. In August 2006, the Integrating the Healthcare Enterprise initiative, with the collaboration of ISO/IEEE11073 and HL7 has released the Patient Care Device Technical Framework.

V. CONCLUSIONS OR FUTURE TRENDS

Unlike ICU scenarios, the telemonitoring environments involve very strict communications restrictions due to particular electronic features as it was discussed in Section II. The ISO/IEEE 11073 standards are evolving in different ways to face the challenge and provide the basis for an open plug-and-play interoperability for telemonitoring systems.

With appropriate attention to achieving semantic interoperability it may be possible for telemonitoring to take its place alongside acute event monitoring to enable a better understanding of the links between lifestyle, genetics, physiology and pathology so that improvements can be made to the management of health problems.

EN ISO/IEEE 11073 standards appear to be best placed to enable such a continuum to be achieved. Furthermore, the authors' believe is that, at this moment, and with the appropriate changes, X73 standards can be applicable to telemonitoring scenarios [29,32]. Even though, there is a need for a wider number of platforms that can demonstrate interoperability using these standards, as well as documented implementation examples and IPOSS (Intellectual Property Open Source Software) modules that can be incorporated in such platforms.

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